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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,994	07/14/2003	Scott Cunningham	2848	5963
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UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHCARE GROUP LP 195 MCDERMOTT ROAD NORTH HAVEN, CT 06473			YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,994

Applicant(s)

CUNNINGHAM ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicants' amendment filed 21 August 2006. The amendment has been considered, however, it does not place the application in condition for allowance. The rejections set forth in the previous Office Action under 35 U.S.C. 103 have been withdrawn in view of the amendment; new grounds for rejection are set forth. The examiner acknowledges the corrections made to the specification and the drawings.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 6, lines 20-21, as well as in Figures 5-7, the side surfaces **28** are not disclosed as "generally convex," and therefore is considered to be new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) in view of **Otsuka et al.**, or **Otsuka** (U.S. Patent No. **5,178,628**).

Claim 1 (currently amended): Guido discloses an elongated needle body **10**, that defines a longitudinal y- axis and x and z axes transverse to the y-axis, and a central shaft **18** having a first end **22** and a second needled end **12** (Figure 2). The needled end **12** has lower and upper opposed surfaces and single side surfaces **70** extending continuously between the lower and upper surfaces and contiguous therewith, wherein the lower and upper surfaces start where the side surfaces begin (Figure 9).

Guido discloses the claimed device except for the upper surface and side surfaces intersecting to define opposed first and second generally convex side cutting edges extending to a pointed tip and the lower surface extending to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip and the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body and terminating at the pointed tip.

Otsuka teaches side surfaces **10b** and **10c** intersecting to define opposed first and second generally convex side cutting edges that extend to a pointed tip **4** and a

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lower surface of body portion that extends to a third cutting edge **11b** defined at the intersection of the side surfaces and proximal of the pointed tip, and also extends in oblique relation relative to the longitudinal axis of the upper surface **5a** (Figure 2 and col. 5, lines 35-40). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the convex side surfaces extending to a pointed tip, as taught by Otsuka, to the device of Guido, since it was known in the art that needles should sharp as possible at the tip and must spread tissue out with the convex side surfaces in order to function properly, which is known in the art since sharper needles require less force and therefore less tissue trauma.

Otsuka also teaches that the third cutting edge that extends in oblique relation relative to the longitudinal axis (col. 5, lines 9-20). It would have been obvious to provide side surfaces extending to a pointed tip and the lower surface extending to a third cutting edge defined at the intersection of the side surfaces, which extends in oblique relation relative to the longitudinal axis, as taught by Otsuka, to Guido since it was known in the art that providing an angle of slope determines the rate at which tissues are cut, and therefore may be altered depending on the application and the particular tissue to be cut.

Claim 2: Guido discloses upper and lower surfaces **70** that are substantially planar (Figures 9-11).

Claim 3: Guido discloses a first transverse cross-sectional dimension adjacent to the central shaft that defines a general trapezoidal configuration (Figure 11).

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Claim 4: Guido lacks a second transverse cross-sectional dimension adjacent the pointed tip defining a general triangular configuration.

However, Otsuka teaches a cross-sectional dimension adjacent to the pointed tip that would have a general triangular configuration (Figure 14). It would have been obvious to one of ordinary skill in the art to use the teaching of Otsuka in the needle of Guido since it was known in the art that the triangular configuration provides long cutting action and to decrease the chance of the needle tip bending.

Claim 10: Guido discloses a needle body that is curved along the longitudinal axis (Figure 2).

Claim 13 (new): Guido discloses the side surfaces being each substantially planar (Figure 9).

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) and **Otsuka** (U.S. Patent No. **5,178,628**), as applied to Claim 1 above, and further in view of **Smith** (U.S. Patent No. **4,513,747**).

Claim 12: Guido and Otsuka lack a linear cutting edge intersecting the upper planar surface at an angle ranging from about 15 to about 30 degrees relative to the longitudinal axis.

Smith teaches an angle of slope **d** between the cutting edge **21** and upper surface **33** that ranges from about 15 to 30 degrees relative to the longitudinal axis (Figure 3, col. 5, lines 4-9). Smith teaches that this range of angles provides ease of passage of the need through the tissue (col. 3, lines 36-38). It would have been

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obvious to modify Guido with the linear cutting edge intersecting the upper planar surface at an angle ranging from 15 to about 30 degrees, as taught by Smith, to Guido and Otsuka in order for the needle to easily pass through tissue.

3. Claims 5-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) and **Otsuka** (U.S. Patent No. **5,178,628**), as applied to Claim 4 above, and further in view of **Munoz** (U.S. Patent No. **5,178,628**).

Claims 5-7 and 14 (new): Guido and Otsuka lack a first cross-sectional dimension defining a dimension along the z-axis corresponding to a first width of the needle end, which is at least equal to a corresponding shaft width of the central shaft, greater than a corresponding shaft width of the central shaft, and not less than about 1.5 times the shaft width and a needled end defining a maximum dimension along the z-axis greater than a corresponding maximum dimension along the z-axis of the central shaft.

Munoz teaches a surgical needle that has a cross-sectional dimension that defines a dimension along the z-axis corresponding to a first width of the needle end, which is at least equal to the corresponding shaft width of the central shaft, is greater than the corresponding shaft width, or a needled end defining a maximum dimension along the z-axis greater than a corresponding maximum dimension along the z-axis of the central shaft (Figures 5A-5C). Although the first width of Munoz is not disclosed as not less than about 1.5 times the shaft width, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the dimension of a first width of the needle end being at least equal to a corresponding shaft width of the central shaft,

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greater than a corresponding shaft width of the central shaft, as taught by Munoz, and not less than about 1.5 times the shaft width, to the combined device of Guido and Otsuka since it was known in the art that the needle end would produce a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily.

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**), **Otsuka** (U.S. Patent No. **5,178,628**), and **Munoz** (U.S. Patent No. **5,178,628**), as applied to Claim 6 above, and further in view of **Naslund** (U.S. Patent No. **4,133,339**).

Claims 8-9: Guido, Otsuka, and Munoz lack a first cross-sectional dimension along an x-axis corresponding to a first height of the needle end, the first height being less than a corresponding shaft height of the central shaft, and not greater than about 0.5 times the shaft height.

Naslund teaches a needle capable of holding sutures that has a thickness ("first height") around a first portion **303**, which is perpendicular to the width (col. 3, lines 27-29), that is less than a corresponding shaft portion **307** and not greater than about 0.5 times the shaft thickness. Naslund teaches that the diminished thickness allows for a corresponding increase in the thickness, and therefore an increase in rigidity of the needle (col. 2, lines 17-21). It would have been obvious to modify Guido, Otsuka, and Munoz with the thickness dimension less than a corresponding shaft portion and not

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greater than about 0.5 times the shaft thickness, as taught by Naslund, because it allows an increase in the thickness of the needle and adds to the rigidity of the needle.

5. Claim 11 rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) and **Otsuka** (U.S. Patent No. **5,178,628**), as applied to Claim 10 above, and further in view of **McGregor et al.** (U.S. Patent No. **4,524,771**).

Claim 11: Guido and Otsuka disclose the claimed device except for the elongated needle shaft defining an angle of curvature ranging from about 80 to about 180 degrees.

McGregor et al. discloses an elongated needle shaft **25** with an angle of curvature within the range of about 80 to about 180 degrees. McGregor et al. teaches that the curve in the needle is helpful in placing the suture by allowing the surgeon to grasp the body of the needle near its center and allows the suture to be placed at a desired depth by a controlled emergence of the needle from the tissue (col. 1, lines 9-24).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide an angle of curvature ranging from about 80 to about 180 degrees to the elongated needle shaft, as taught by McGregor et al., to the combined device of Guido and Otsuka in order to facilitate placing the suture in the tissue to be closed at a desired depth.

6. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) in view of **Munoz** (U.S. Patent No. **5,762,811**).

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Claim 15 (new): Guido discloses an elongated needle body **10**, that defines a longitudinal y- axis and x and z axes transverse to the y-axis, and a central shaft **18** having a first end **22** and a second needled end **12** (Figure 2). The needled end **12** has lower and upper opposed surfaces and single side surfaces **70** extending continuously between the lower and upper surfaces and contiguous therewith, wherein the lower and upper surfaces start where the side surfaces begin (Figure 9).

Guido discloses the claimed device except for the upper surface and single side surfaces intersecting to define opposed first and second generally arcuate side cutting edges extending to a pointed tip and the lower surface extending to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip and the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body and terminating at the pointed tip, the second needled end defining a maximum dimension inclusive of the first and second cutting edges greater than a corresponding maximum dimension of the central shaft.

Munoz teaches single side surfaces intersecting to define opposed first and second generally arcuate side cutting edges that extend to a pointed tip and a lower surface of body portion that extends to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip, and also extends in oblique relation relative to the longitudinal axis of the upper surface (Figures 5A-5C). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the side surfaces extending to a pointed tip, as taught by Munoz, to the device of Guido, since it was known in the art that needles should sharp as possible at the tip and must

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spread tissue out with the arcuate side surfaces in order to function properly, which is known in the art since sharper needles require less force and therefore less tissue trauma.

Munoz also teaches that the cutting edge that extends in oblique relation relative to the longitudinal axis serves as an angle of slope which determines the rate at which tissues are cut, and therefore may be altered depending on the application and the tissue to be cut (Figures 5A-5C). It would have been obvious to provide side surfaces extending to a pointed tip and the lower surface extending to a cutting edge defined at the intersection of the side surfaces, which extends in oblique relation relative to the longitudinal axis, as taught by Munoz, to Guido since it was known in the art that providing an angle of slope determines the rate at which tissues are cut, and therefore may be altered depending on the application and the particular tissue to be cut.

Claim 16 (new): Guido discloses the side surfaces being each substantially planar (Figure 9).

Claim 17 (new): Guido discloses the claimed device except for the third cutting edge being substantially linear.

Munoz teaches a third cutting edge being substantially linear (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a substantially linear third cutting edge, as taught by Munoz, to Guido since it was known in the art that a linear cutting edge permits long cutting action and less likelihood of bending or deformation of the tip.

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Claim 18 (new): Guido discloses the second needle end defining a first transverse cross-sectional dimension adjacent the central shaft, the first cross-sectional dimension defining a general trapezoidal configuration (Figures 10-11).

Claim 19 (new): Guido discloses second needle end defining a first transverse cross-sectional dimension adjacent the central shaft, the first cross-sectional dimension defining a general triangular configuration (Figures 4-5).

Claim 20 (new): Guido discloses the claimed device except for the maximum dimension of the second needled end is at least about 1.5 times the maximum dimension of the central shaft.

Although Munoz does not disclose for the maximum dimension of the second needled end is at least about 1.5 times the maximum dimension of the central shaft, it would have been obvious to one of ordinary skill in the art to modify Guido with this dimension since it was known in the art that the needle end would produce a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily.

Response to Arguments

6. Applicant's arguments with respect to Claims 1-12 have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER